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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,533	03/15/2004	Vanessa I. China	200315755-1	1334

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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05/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/800,533	Applicant(s) CHINEA, VANESSA I.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) 1-5 and 10-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 6-9 and 25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1618

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 12/26/06 wherein claims 6 and 7 were amended and claim 25 was added.

Note: Claims 1-25 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments and/or amendment filed 12/26/06 to the rejection of claims 6-9 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed found persuasive-in-part for the reasons set forth below.

112 Second Paragraph Rejections

The 112 second paragraph rejection of claims 6-9 is WITHDRAWN.

103 Rejection

I. The rejection of claims 6-9 and newly added 25 under 35 USC 103(a) as being unpatentable over Patel et al (US Patent No. 6,294,192) is MAINTAINED for reasons of record in the office action mailed 9/25/06 and those set forth below.

II. The rejection of claims 6-9 and newly added 25 under 35 USC 103(a) as being unpatentable over Gardella et al (US Patent No. 4,002,718) in view of Patel et al (US Patent No. 6,294,192) is MAINTAINED for reasons of record in the office action mailed 9/25/06 and those set forth below.

Applicant asserts that neither Patel et al nor Gardella et al teaches 'a pharmaceutical solution stream ejected from a thermal fluid ejection device' as recited in independent claim 6.

First, review of independent claim 6 results in one not being able to ascertain what is being claimed. Was Applicant attempting to write a product-by-process claim? If so, Applicant is reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious form a product of the art, the claim is unpatentable even though the prior art product was made by a different process (see MPEP 2113).

Secondly, if Applicant reviews Patel et al, column 26, lines 55-59, for example, it discloses that the compositions of their invention may be formulated as a spray or aerosol. The compositions may be formulated as a sprayable solution, such formulation is particularly useful for spraying to coat a multiparticulate carrier, such as a bead. Thus, a pharmaceutical solution stream would be obvious.

Furthermore, since both Applicant and the cited prior art disclose the same components in a solution (i.e., a pharmaceutical comprising digoxin and 2-pyrrolidone) the properties of both Applicant and the prior art composition would be the same since a composition is inseparable from its properties.

NEW GROUNDS OF REJECTION

112 First Paragraph (New Matter)

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1618

4. Claims 7 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to state that the component includes a Class 3 solvent. Applicant's asserts that Class 3 solvents are supported in the specification because the specification discloses websites that include such solvents. It should be noted that one cannot arbitrarily select a class of solvents when the specification itself never discloses the used of a Class 3 solvent. Applicant is respectfully requested to review MPEP 706.03(o).

WITHDRAWN CLAIMS

5. Claims 1-5 and 10-24 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

COMMENTS/NOTES

6. Amended independent claim 6 is directed to a pharmaceutical solution comprising a pharmaceutical solution stream comprising an active pharmaceutical ingredient and a vehicle. Actually, the components present in the pharmaceutical solution stream are the same components that were present in the pharmaceutical solution of the originally filed claims.

OBJECTION TO THE SPECIFICATION

7. The disclosure is once again objected to because of the following informalities: the disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code (see MPEP 608.01).

Note: In the amending of the specification in the amendment filed 12/26/06, Applicant replaced the originally filed hyperlinks with other hyperlinks. Applicant is respectfully requested to delete the embedded hyperlinks and/or other browser-executable codes.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

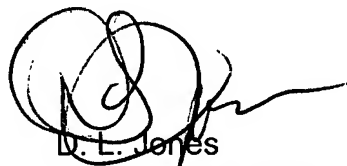
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1618

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

May 11, 2007